FEED UNIT

SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

MINUTES OF THE 161st FEEDAP PLENARY MEETING

Webconference, 4 May 2022

(Agreed by written procedure on 10 May 2022)

Participants

- **Panel Members**:

  Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Roberto Edoardo Villa and Ruud Woutersen.

- **Hearing Experts:**

  N/A

- **European Commission**

  Marta Ponghellini (DG SANTE)

- **EFSA:**

  FEED Team: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Yolanda García Cazorla, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Paola Manini, Jordi Ortuño, Elisa Pettenati, Fabiola Pizzo, Daniel Plaza, Martina Reitano, Joana Revez, Barbara Rossi, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

  KNOW Team: Angelo Maggiore

- **Others:**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without modifications.

European Food Safety Authority
Via Carlo Magno 1A – 43126 Parma, Italy
Tel. +39 0521 036 111
info@efsa.europa.eu | www.efsa.europa.eu

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since the 160th FEEDAP Plenary meeting

The minutes of the 160th FEEDAP Plenary meeting were agreed by written procedure on 30 March 2022[3].

5. Scientific topics for discussion

5.1. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Cassia oil (EFSA-Q-2010-01296, EFSA-Q-2022-00104)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Cassia oil as a sensory additive for all animal species.

The draft opinion was discussed. The Panel agreed that further discussion is needed.

5.2. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Cinnamon oil (EFSA-Q-2010-01296, EFSA-Q-2022-00105)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Cinnamon oil as a sensory additive for all animal species.

The draft opinion was discussed. The Panel agreed that further discussion is needed.

5.3. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Pepper oil and Pepper oleoresin (EFSA-Q-2010-01296, EFSA-Q-2022-00106)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Pepper oil and Pepper oleoresin as a sensory additive for all animal species.

The draft opinion was discussed. The Panel agreed that further discussion is needed.

5.4. Sepiolitic clay for all animal species (EFSA-Q-2019-00431)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of sepiolitic clay as a technological additive for all animal species.

1 Policy on Independence
2 Competing Interest Management
3 https://www.efsa.europa.eu/sites/default/files/2022-04/feedap20220323-24_m.pdf

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.5. BIO-THREE® (*Bacillus subtilis* TO-A (BS), *Enterococcus faecium* T-110 (EF), *Clostridium butyricum* TO-A (CB)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species (EFSA-Q-2020-00556)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of BIO-THREE® (*Bacillus subtilis* TO-A (BS), *Enterococcus faecium* T-110 (EF), *Clostridium butyricum* TO-A (CB)) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.6. Alpha-amylase from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251, *Aspergillus oryzae* CBS 585.94 and *Aspergillus oryzae* ATTC SD-5374, endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001, *Trichoderma reesei* ATCC SD-6331 and *Aspergillus niger* CBS 120604, endo-1,4-beta-xylanase from *Trichoderma koningii* MUCL 39203 and *Trichoderma longibrachiatum* CBS 614.94 and endo-1,3(4)-beta-glucanase from *Aspergillus tubingensis* MUCL 39199 for all animal species (EFSA-Q-2020-00836)

EFSA was requested to deliver an opinion on the safety and efficacy of Alpha-amylase from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251, *Aspergillus oryzae* CBS 585.94 and *Aspergillus oryzae* ATTC SD-5374, endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001, *Trichoderma reesei* ATCC SD-6331 and *Aspergillus niger* CBS 120604, endo-1,4-beta-xylanase from *Trichoderma koningii* MUCL 39203 and *Trichoderma longibrachiatum* CBS 614.94 and endo-1,3(4)-beta-glucanase from *Aspergillus tubingensis* MUCL 39199 as a technological additive for all animal species based on the additional information provided by the applicant.

The draft opinion was discussed. The Panel agreed that further discussion is needed.

5.7. Nutrase P (6-phytase) for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds (EFSA-Q-2021-00538)

EFSA was requested to deliver an opinion on the safety and efficacy of Nutrase P (6-phytase) as a zootechnical additive for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds based on the additional information provided by the applicant.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

6. New mandates

6.1. New Applications under Regulation (EC) 1831/2003 since the previous meeting

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. These applications were presented to the Panel:

EFSA-Q-Number	Subject
EFSA-Q-2022-00220	BIOSPRINT® (4b1710 - *Saccharomyces cerevisiae* MUCL 39445) for cats and dogs
EFSA-Q-2022-00221	TechnoSpore50 (*Weizmannia coagulans* DSM 32016) for poultry reared for breeding, poultry reared for laying, poultry for fattening, ornamental birds, suckling and weaned Suidae piglets

6.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

EFSA-Q-Number	Subject	Valid on
EFSA-Q-2021-00128	AGal-Pro BL and AGal-Pro BL-L (alpha-galactosidase (EC3.2.1.22), endo-1,4-betaglucanase (EC3.2.1.4)) for chickens and minor poultry species for fattening and chickens reared for laying	22/03/2022
EFSA-Q-2021-00383	CanBiocin k-9 Heritage Probiotic Blend for dogs	01/04/2022
EFSA-Q-2021-00467	Nor-Grape alpha (dry grape extract) for all avian species	07/04/2022
EFSA-Q-2021-00472	Coxiril (diclazuril) for chickens for fattening, turkeys for fattening, other - guinea fowl for fattening and breeding	20/04/2022
EFSA-Q-2021-00688	Renewal of urea authorisation as a feed additive for ruminants	25/03/2022
EFSA-Q-2022-00006	*Pediococcus pentosaceus* DSM 23376 for all animal species	13/04/2022

These applications were assigned to the respective working groups, where relevant.

6.3. New questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2022-00232	Chlorophyllin Copper Complex E 141 for cats and dogs
EFSA-Q-2022-00233	Correlink™ (*Bacillus subtilis* ABS747) for Chickens for fattening, Turkeys for fattening, Chickens reared for laying, Turkeys reared for breeding, Minor poultry species
EFSA-Q-2022-00234	Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 in all animal species

These questions were assigned to the respective working groups, where relevant.

7. Feedback from Scientific Committee/Scientific Panels, EFSA or the European Commission

7.1. Scientific Committee/Scientific Panels

The Chair of the Panel provided an overview of the main topics discussed during the last plenary meeting of the Scientific Committee (SC).

- The SC endorsed the report on a common approach on exposure assessment methodologies to residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin, which was prepared by a joint WG EFSA-EMA. The report will be subject to public consultation.
- The SC also endorsed for public consultation the draft review of the existing health-based guidance values for copper and its exposure assessment from all sources.
- Two new mandates were received, one for a scientific report on dietary exposure to metals and iodine in seaweed and halophytes in the European population and one on the risks for human health related to the presence of bromide ion in food/feed.
- The SC also discussed on the priorities for the work programme 2022-2024.

7.2. EFSA

Not discussed.

7.3. European Commission

Not discussed.

8. Other scientific topics for information/or discussion

The Panel was informed on the project regarding vulnerabilities of the circular economy (CE) for food and feed safety, plant, animal health and the environment, in the context of the Emerging Risks Identification process. EFSA has outsourced an extensive literature review to gather evidence and a large stakeholder's network is under construction. The extensive literature search conducted in the first part of the project will be complemented with other consultation processes aiming at refining the emerging risks identification and characterisation. In the course of one of these consultations, it was decided to focus on feed derived from food waste, former food products and food processing by-products. A foresight workshop on "Circular future: emerging feed sources, technologies and related risks" has been announced, scheduled on-line for 9-10 June.

9. Any other business

9.1. Compliance of tolerance and efficacy studies in target species with the provisions of Directive 63/2010/EU on the protection of animals used for scientific purposes

The Guidance on the safety for the target species and the Guidance on the assessment of the efficacy of feed additives both require that "Studies should be performed and documented according to appropriate quality standards and should respect the rules on animal welfare laid down by EU legislation, particularly those listed in Directive 63/2010/EU". This compliance should be clearly

indicated/reported in the report of the studies by i) the ethical statement, indicating compliance with relevant guidelines for the care and use of animals, ii) housing and husbandry conditions in which the animals were kept during the study and iii) experimental procedures followed during the study.

The Panel wishes also to raise the attention of applicants on the compliance and reporting on these aspects in the study reports sent for assessment, as it is the responsibility of the applicant to ensure that these provisions are respected in the conduct/reporting of the studies.

9.2. Implementation of the guidance of the Scientific Committee regarding nanoparticles

The Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017), under section 2.1.5, contains provisions for the assessment of the presence of nanoparticles. In 2021, the Scientific Committee of EFSA has adopted a Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles which applies to all regulated food and feed product areas (EFSA Scientific Committee, 2021a). In order to align the requirements for the assessment of small particles including nanoparticles, the Panel considers that the following changes should be introduced in the Guidance on the identity, characterisation and conditions of use of feed additives:

In section 2.1.5. Physical state of each form of the product

The text:

"If the nature of the additive allows the possibility of the presence of nanoparticles, initially a particle size analysis of the additive by laser diffraction should be made. If the particle size analysis of the additive indicates that more than 1% of particles below 1 µm are present, this fraction should be further characterised by scanning electronic microscopy (wet method). Results should be expressed as a proportion of total number of particles. It should be clearly indicated if the product is a nanomaterial as defined by European legislation."

is replaced by:

"For all additives (with the exception of additives consisting only of microorganisms), data should be provided to assess the presence of small particles including nanoparticles following the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021a). In case the additive does not meet at least one of the Decision criteria listed in Table 1 of that Guidance, a full assessment for the fraction of small particles should be conducted in line with the requirements established in the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain, human and animal health (EFSA Scientific Committee, 2021b), including additional information on the physico-chemical characterisation of the additive.

For additives consisting of (or containing) engineered nanomaterials as defined in in Regulation (EU) No 2015/2283 (the Novel Food Regulation), the risk assessment including the physico-chemical characterisation of nanomaterial should follow the provisions of the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain, human and animal health (EFSA Scientific Committee, 2021b)."

These changes will be revised and implemented in a future update of the guidance.

EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017. Guidance

on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023

EFSA Scientific Committee, More S, Bampidis V, Benford D, Bragard C, Halldorsson T, Hernandez-Jerez A, Bennekou SH, Koutsoumanis K, Lambré C, Machera K, Naegeli H, Nielsen S, Schlatter J, Schrenk D, Silano (deceased) V, Turck D, Younes M, Castenmiller J, Chaudhry Q, Cubadda F, Franz R, Gott D, Mast J, Mortensen A, Oomen AG, Weigel S, Barthelemy E, Rincon A, Tarazona J and Schoonjans R, 2021a. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. https://doi.org/10.2903/j.efsa.2021.6769

EFSA Scientific Committee, More S, Bampidis V, Benford D, Bragard C, Halldorsson T, Hernández-Jerez A, Hougaard Bennekou S, Koutsoumanis K, Lambré C, Machera K, Naegeli H, Nielsen S, Schlatter J, Schrenk D, Silano V, Turck D, Younes M, Castenmiller J, Chaudhry Q, Cubadda F, Franz R, Gott D, Mast J, Mortensen A, Oomen AG, Weigel S, Barthelemy E, Rincon A, Tarazona J and Schoonjans R 2021b. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. https://doi.org/10.2903/j.efsa.2021.6768